

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	BUCHANAN <i>ET AL.</i>	)		
		)		
App. Serial No.:	Rule 1.53(d) Divisional of	)	Confirmation No.	Unassigned
	Application No. 09/843,037	)		
	Filed April 26, 2001	)	Group Art Unit:	Unassigned
		)		
Filed:	Concurrently	)	Examiner:	Unassigned
		)		
Title:	ACYLATED CYCLODEXTRIN:	)		
	GUEST MOLECULE	)		
	INCLUSION COMPLEXES	)		

**INFORMATION DISCLOSURE STATEMENT**

MAIL STOP PATENT APPLICATION  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859

September 30, 2003

Sir:

Pursuant to the requirements of 37 C.F.R. § 1.56, submitted herewith on the accompanying Form PTO 1449 is a listing of documents known to Applicants and/or their attorneys. All of the documents cited were cited by or submitted to the Patent Office in Application No. 09/843,037, filed April 26, 2001, to which the present application claims priority. Pursuant to 37 C.F.R. § 1.98(d), copies of these documents are not enclosed.

**ATTORNEY DOCKET NO.: 05015.0366U4**  
**APPLICATION NO.: Rule 1.53(d) Divisional of**  
**Application No. 09/843,037**  
**Filed April 26, 2001**

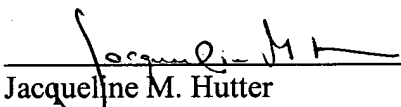
This Information Disclosure Statement is believed to be filed in a timely manner pursuant to 37 C.F.R. § 1.97(b)(1), in that this Information Disclosure Statement is being filed within three months of the filing date of the present patent application.

Consideration of the cited documents and making the same of record in the prosecution of the above-referenced application are respectfully requested.

Included herewith is payment in the amount of \$1,452.00 for the Application filing fee. This payment is to be charged to a credit card and such payment is authorized by the signed, enclosed document entitled: Credit Card Payment Form PTO-2038. No additional fee is believed to be due; however, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment in fees to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

  
\_\_\_\_\_  
Jacqueline M. Hutter  
Registration No. 44,792

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859  
(678) 420-9300 Phone  
(678) 420-9301 Fax

**ATTORNEY DOCKET NO.: 05015.0366U4**  
**APPLICATION NO.: Rule 1.53(d) Divisional of**  
**Application No. 09/843,037**  
**Filed April 26, 2001**

**CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. § 1.10**

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as Express Mail, Label No. EL992019711US, in an envelope addressed to: MAIL STOP PATENT APPLICATION, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

  
\_\_\_\_\_  
Michael Laird

9/30/03  
\_\_\_\_\_  
Date

Form PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rev. 7-80) PATENT AND TRADEMARK OFFICE  <b>LIST OF PRIOR ART CITED BY APPLICANT</b> (Use several sheets if necessary)	ATTORNEY DOCKET NO.:	05015.0366U4	SERIAL NO.	Unassigned
	APPLICANT:	Buchanan <i>et al.</i>	CONFIRMATION NO.	Unassigned
	FILING DATE:	09/22/2003	GROUP:	Unassigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIALS		DOCUMENT NO.	DATE	NAME	C L A S S	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	6,046,177	04/04/2000	Stella, <i>et al.</i>			
	A2	6,019,988	02/01/2000	Parab, <i>et al.</i>			
	A3	6,010,715	01/04/2000	Wick, <i>et al.</i>			
	A4	5,980,551	11/09/1999	Summers, <i>et al.</i>			
	A5	5,904,929	05/18/1999	Uekama, <i>et al.</i>			
	A6	5,865,792	02/02/1999	Ledger <i>et al.</i>			
	A7	5,817,332	10/06/1998	Urtti, <i>et al.</i>			
	A8	5,633,368	05/27/1997	Hirse Korn			
	A9	5,614,199	03/25/1997	Zmitek, <i>et al.</i>			
	A10	5,383,928	01/24/1995	Scott, <i>et al.</i>			
	A11	5,298,496	03/29/1994	Vikmon <i>et al.</i>			
	A12	4,956,351	09/11/1990	Mesens <i>et al.</i>			
	A13	4,948,395	08/14/1990	Armstrong			
	A14	4,727,064	02/23/1988	Pitha			
	A15	4,722,815	02/02/1988	Shibani			
	A16	4,670,419	06/02/1987	Uda <i>et al.</i>			
	A17	4,518,588	05/21/1985	Szejtli <i>et al.</i>			
	A18	4,073,931	02/14/1978	Akito, <i>et al.</i>			
	A19	3,459,731	08/05/1969	Gramera <i>et al.</i>			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS		DOCUMENT NO.	DATE	NAME	C L A S S	SUBCLASS	FILING DATE IF APPROPRIATE
	A20	WO 98/18610	05/07/1998	PCT			
	A21	EP 0578231	01/12/1994	Europe			
	A22	10-045609	02/17/1998	Japan (abstract)			
	A23	58-108201	09/14/1983	Japan (abstract)			

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	A24	Bauer <i>et al.</i> "Chemical Stabilization of a Vasoactive S-Nitrosothiol with Cyclodextrins Without Loss of Pharmacologic Activity," <i>Pharm. Res.</i> , 8(10):1329-1334, 1991
	A25	Bertele <i>et al.</i> "Prostanoids for Chronic Critical Leg Ischemia - A Randomized, Controlled, Open-Label Trial with Prostaglandin E <sub>1</sub> " <i>Ann Intern Med.</i> , 130:412-421 (1999)
	A26	Caplus abstract document number 98:40477 (1983)

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
A27	French <i>et al.</i> "Studies on the Schardinger Dextrins. The Preparation and Solubility Characteristics of Alpha, Beta and Gamma Dextrins <sup>1</sup> ," <i>JACS</i> , 71:353-356 (1949)	
A28	Freudenberg <i>et al.</i> "Schardinger's Dextrins Derived from Starch," <i>Chem. Ind.</i> , 731-735 (November 29, 1947)	
A29	Freudenberg <i>et al.</i> "Ober Schardingers Dextrine aus Starke," <i>Annalea</i> , 518:102-108 (1935)	
A30	Fucile <i>et al.</i> "Inclusion Complex of Isosorbide-5-mononitrate in $\beta$ -Cyclodextrin: Comparison of Preparation Methods and Assessment of Analytical Techniques," <i>Eur. J. Pharm. Biopharm.</i> , 38(4):140-144 (1992)	
A31	Harata. "X-Ray Structure of Hexakis (2,3,6-tri-O-acetyl)- $\alpha$ -cyclodextrin," <i>Chem. Ltrs.</i> , 589-590 (1998)	
A32	Hirayama <i>et al.</i> "Characterization of Peracylated $\beta$ -Cyclodextrins with Different Chain Lengths as a Novel Sustained Release Carrier for Water-Soluble Drugs," <i>Chem. Pharm. Bull.</i> , 43(1):130-136 (1995)	
A33	Hirayama <i>et al.</i> "Utilization of Diethyl- $\beta$ -Cyclodextrin as a Sustained-Release Carrier for Isosorbide Dinitrate," <i>J. Pharm. Sci.</i> , 77(3):233-236 (March 1988)	
A34	Hirayama <i>et al.</i> , "Release control of 16, 16-dimethyl-trans-delta2-prostaglandin E1 methyl ester by cyclodextrin complexation," <i>Kobunshi Ronbunshu</i> , 39(10):643-648 (1982)	
A35	Idzu <i>et al.</i> "Stability and Bioequivalency of Sublingual Tablet of Nitroglycerin - $\beta$ -cyclodextrin Coomplex," <i>Jpn. J. Hosp. Pharm.</i> , 15(1):36-42 (1989)(Abstract)	
A36	Matsubara <i>et al.</i> "Controlled Release of the LHRH Agonist Buserelin Acetate from Injectble suspensions Containing Triacetylated Cyclodextrins in an Oil Vehicle," <i>J. Controlled Rel.</i> , 31:173-180 (1994)	
A37	Nakanishi <i>et al.</i> "Sustained Release of Flufenamic Acid from a Drug-Triacetyl- $\beta$ -Cyclodextrin Complex," <i>Biol. Pharm. Bull.</i> , 20(1):66-70 (1997)	
A38	Soliman <i>et al.</i> "Controlled Release of Diltiazem by a Combination of Short-and Long-chain Peracylated $\beta$ -Cyclodextrins in Dogs," <i>Pharm. Sci.</i> , 2:533-536 (1996)	
A39	Stadler-Szoke <i>et al.</i> "A nitroglycerin $\beta$ -ciklodextrin zarvanykomplex," <i>Acta Pharmaceutica Hungarica</i> , 49:30-34 (1979)	
A40	Szejtli, "Chemistry, Physical and Biological Properties of Cyclodextrins," pp. 5-40 (date unknown)	
A41	Tomono <i>et al.</i> "Effect of $\beta$ -Cyclodextrins on Sustained Release of Nitroglycerin from Ointment Bases," <i>Yakuzaigaku</i> , 51(1):22-28 (1991) (Abstract)	
A42	Tomono <i>et al.</i> "Interaction of Nitroglycerin with 6-O- $\alpha$ -maltosylcyclomaltoheptaose," <i>Carb. Res.</i> , 192:351-356 (1989)	
A43	Tomono <i>et al.</i> "Complexation of Nitroglycerin with Several $\beta$ -Cyclodextrin Polymers by Grinding Method," <i>Yakuzaigaku</i> , 48(1):9-16 (1988) (Abstract)	
A44	Uekama <i>et al.</i> "Peracylated $\beta$ -Cyclodextrins as Novel Sustained-release Carriers for a Water-soluble Drug, Molsidomine" <i>J. Pharm. Pharmacol</i> , 46:714-717 (1994)	
A45	Uekama <i>et al.</i> "Stabilization of isosorbide 5-mononitrate in solid state by $\beta$ -cyclodextrin complexation," <i>Intl. J. Pharm.</i> , 25:339-346 (1985)	
A46	Uekama <i>et al.</i> "Improvement of Dissolution Characteristics and Chemical Stability of Prostaglandin E <sub>1</sub> by Y-Cycodextrin Complexation," <i>Chem. Pharm. Bull.</i> , 32(1):275-279 (1984)	
A47	Umemura <i>et al.</i> "Effect of Diethyl- $\beta$ -Cyclodextrin on the Release of Nitroglycerin from Formulations," <i>Drug Des. Del.</i> , 6:297-310 (1990)	
A48	Yamamoto <i>et al.</i> "Improvement of Stability and Dissolution of Prostaglandin E by Maltosyl- $\beta$ -Cyclodextrin in Lyophilized Formulation," <i>Chem. Pharm. Bull.</i> , 40(3):747-751 (1992)	
EXAMINER: _____ DATE CONSIDERED: _____		
EXAMINER: Initial if reference considered whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		